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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,322	08/22/2001	Phuong Grace Dang	452005-13	1448

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,322	DANG ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-22 and 31-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-22 and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt Request for Continued Examination and Amendments/Remarks filed January 12, 2005 is acknowledged. Claims **15-22 and 31-34** are pending in this application.

Miscellaneous Remarks

It should be noted that applicant's representative's remarks regarding the examiner's prosecution history and the subsequent patents allowed is *inappropriate* since it does not pertain to the prosecution of the instant application. Further, as applicant's representative is well aware of, the prosecution history of each patent is complex and unique. Thus, it is *inappropriate* for applicant's representative to make statements and assumptions on patents that have been issued by the examiner without knowing the prosecution history of a particular patent. The examiner suggests that the applicant's representative present arguments that are relevant since the examiner will not comment on patents that are irrelevant to the prosecution of the instant application.

With regard to the intended use limitations, the examiner suggests reading the last office action carefully wherein it should be noted that the examiner neither requested nor mandated that the applicant remove the intended use limitations. The examiner merely pointed out that intended use without structural limitations in product claims and not the instant method claims, are not given patentable weight. Lastly, it is pointed out that the phrase "pharmaceutically effective amount" was not rejected under indefiniteness; the phrase "pharmaceutically effective amount being one half the daily dosage" was rejected in claims 23-26 only. Thus, applicant's deletion of

the phrase "pharmaceutically effective amount" in all the claims to "placate the examiner" was unnecessary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-22 and 31-34 under are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/22762 in view of Chopdekar et al (5,663,415) and in further view of Sims et al (5164398).

WO teaches a taste-masked pharmaceutical composition. WO teaches the method of reducing or abating the symptoms associated with the common cold, respiratory disorders, etc. See page 1, lines 33-36. WO teaches tablets or liquid dosage forms. See page 5, lines 25-27. Example II teaches a syrup composition containing 0.1323% dextromethorphan HBr, 1.3230% guaifenesin, and other pharmaceutical excipients. Examples of antitussives taught are dextromethorphan, cholpendianol, carbetapentane, etc. and their salts. See page 4, lines 24-29. WO teaches that substantially similar results are also obtained by replacing the exemplified actives such as dextromethorphan. See page 9, lines 20-27. WO refers to US patent 4,619,934 for the dosage amounts of the decongestants, antihistamines, expectorants, and antitussives that are utilized. US '934 teaches the use of 100mg guaifenesin.

WO does not exemplify specify the use of the salt derivative, carbetapentane tannate or the dosage amount.

Chopdekar et al teach antihistamine tannates since this form is stable and may be administered in its form without any side effects. See column 1, lines 15-18. The antihistamine reacted with the tannic acid may be carbetapentane, among others. See column 3, line 3.

Sims et al teach a pharmaceutical composition containing an analgesic, an antitussive, and expectorant for the relief of cough and cold symptoms (co. 1, lines 30-65). Sims teaches dextromethorphan or carbetapentane or its salt including tannate as the antitussive agent (col. 2, line 39). Guaifenesin is taught as one of the expectorants that can be used. Sims teaches the composition in the form of a tablet or suspension (col. 3, lines 40-41). The antitussive is utilized in the amount of 1-50 mg depending on the specific antitussive used and the expectorant in the amount of 100-1000 mg. See column 3, lines 30-40.

Firstly, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to substitute dextromethorphan with carbetapentane in WO's example II. One would be motivated to do so with the expectation of similar results since WO teaches that both dextromethorphan and carbetapentane are antitussives and teaches that functionally equivalent forms of the exemplified active agents may be replaced. Therefore, it is deemed prima facie obvious to substitute one functionally equivalent agent with another equivalent agent since both are known in the art for the same functional purpose.

Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings of Chopdekar et al and utilize the tannate salt of carbetapentane. One would have been motivated to do so since Chopdekar teaches the tannate salt form is more stable and has less side effects. Therefore, one would have been motivated to use the tannate form to yield a stable composition. Further, one would expect similar results

since WO teaches that the pharmaceutical acceptable salts of the antitussives are suitable for use in the composition.

Lastly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Sims teachings and utilize the instant dosage ranges. One would have been motivated to utilize the instant ranges since Sims teaches this is the suitable and conventional range of the cough agents in cold remedy formulations. Note that the recitation of "about" permits some tolerance of about ± 10 degrees. *In re Ayers*, 154 F 2d 182, 69 USPQ 109 (CCPA 1946).

With regard to the method of administering the tablets twice-a-day, it is deemed obvious to one of ordinary skill in the art to effective dosage amount by either administering the entire one-day dosage of the medication at one time or dividing it into multiple dosages since the criticality lies in administering the "effective and maximum" dosage rather than how many times it is administered.

Response to Arguments

Applicant argues that Chopdekar teaches antihistamine tannates and erroneously lists carbetapentane as part of the Markush group. Applicant argues that one would not have been motivated to look to a reference such as Chopdekar, which teaches antihistamines. Applicant argues that the examiner has misconstrued Chopdekar's disclosure and the reference does not teach that tannate salts are stable. Applicant argues that dextromethorphan and carbetapentane tannate are not functional equivalents since not all coughs are the same.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner points out that the applicant has not provided any evidence of Chopdekar's

"erroneous" listing of carbetapentane. The examiner acknowledges that the art predominantly categorizes carbetapentane as an antitussives; however it is also pointed out that a patentee is allowed to be his own lexicographer. Thus, regardless of the prior art calling the compound (carbetapentane) an antihistamine or an antitussive, it does not change the chemical structure of the compound. Therefore, the fact that Chopdekar teaches tannates are stable is still applicable.

Secondly, as acknowledged by the applicant Chopdekar teaches "Antihistamine compounds in the form of their free bases as well as their salts, e.g. hydrochloride, maleate, tannate, etc. are well known. Frequently, it is desirable to utilize the antihistamine in the form of its tannate salt, because such salt is generally quite stable and may be administered in such form without any untoward side effects." It is quite clear that Chopdekar teaches tannate salt are stable without any ambiguity as argued by the applicant. Thus, the examiner's motivation to utilize the instant salt, is in fact, provided by the prior art itself.

Again, as stated in the Final Office Action, the examiner did not contend that that hydrobromides and tannates are functional equivalents. A close reading of the rejection reveals that the examiner is stating that carbetapentane and dextromethorphan are functional equivalents and it is obvious to substitute dextromethorphan with instant carbetapentane. The examiner relies on Chopdekar for the motivation to utilize a tannate salt.

With regard to the argument that dextromethorphan and carbetapentane are not equivalent since "not all coughs are the same", the examiner has points out that the claims do not recite the type of cough to be treated. Thus, this argument is moot since applicant is relying on a feature that is not claimed.

The examiner points out that mere allegations of novelty and unobviousness, will not overcome an obviousness rejection. The examiner suggests unexpected results to overcome the instant rejection such as a comparison of the inventive composition containing instant guaifenesin and carbetapentane to the prior art's composition containing dextromethorphan and guaifenesin.

With regard to the teachings of Sims, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In instant case, the fact that Sims teaches ibuprofen is not relevant since the examiner relies on Sims for its specific teachings of the dosage amount of an antitussive.

Accordingly, the rejection is maintained.

Claims 15-22 and 31-34 under are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/22762 in view of Leflein et al (6,417,206).

WO teaches a taste-masked pharmaceutical composition. WO teaches the method of reducing or abating the symptoms associated with the common cold, respiratory disorders, etc. See page 1, lines 33-36. WO teaches tablets or liquid dosage forms. See page 5, lines 25-27. Example II teaches a syrup composition containing 0.1323% dextromethorphan HBr, 1.3230% guaifenesin, and other pharmaceutical excipients. Examples of antitussives taught are dextromethorphan, cholpendianol, carbetapentane, etc. and their salts. See page 4, lines 24-29. WO teaches that substantially similar results are also obtained by replacing the exemplified

actives such as dextromethorphan. See page 9, lines 20-27. WO refers to US patent 4,619,934 for the dosage amounts of the decongestants, antihistamines, expectorants, and antitussives that are utilized. US '934 teaches the use of 100mg guaifenesin.

WO does not exemplify specifically the use of the salt derivative, carbetapentane tannate or the dosage amount.

Leflein et al teach an antitussive, antihistamine, and decongestant composition. Specifically, Leflein teaches a combination of carbetapentane tannate, pyrilamine tannate, and phenylephrine tannate for the relief of cough associated with the common cold. See abstract. Leflein teaches carbetapentane is a known antitussive that depresses the cough reflex. Further, the reference teaches antitussives, antihistamines, and decongestants in the form as frees bases as well as their salts, i.e. hydrochloride, citrate, maleate and tannate are well known. Leflein teaches that the tannate salt are very desirable since such salts are generally stable and may be combined in such forms without any untoward side effects. See column 1, line 25 to column 2, lines 2. Leflein teaches the tablet form usually contains 50-75 mg of carbetapentane tannate and a suspension contains 20-30mg of carbetapentane tannate. See column 2, lines 27-41.

Firstly, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to substitute dextromethorphan with carbetapentane in WO's example II. One would be motivated to do so with the expectation of similar results since WO teaches that both dextromethorphan and carbetapentane are antitussives and teaches that functionally equivalent forms may of the exemplified active agents may be replaced. Therefore, it is deemed prima facie obvious to substitute one functionally equivalent agent with another equivalent agent since both are known in the art for the same functional purpose.

Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings of Leflein et al and utilize the tannate salt of carbetapentane. One would have been motivated to do so since Leflein teaches the tannate salt form is more stable and may be combined without in such as form without side effects. Therefore, one would have been motivated to use the tannate form to yield a stable composition. Further, one would expect similar results since WO teaches that the pharmaceutical acceptable salts of the antitussives are suitable for use in the composition. Further, Leflein teaches the conventional dosage amount of carbetapentane tannate in both solid and dosage forms.

With regard to the method of administering the tablets twice-a-day, it is deemed obvious to one of ordinary skill in the art to effective dosage amount by either administering the entire one-day dosage of the medication at one time or dividing it into multiple dosages since the criticality lies in administering the "effective and maximum" dosage rather than how many times it is administered.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

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